Guidance for Industry

Veterinary Feed Directive
Common Format
Questions and Answers

Submit comments on this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2010-N-0155.

For further information regarding this document, contact AskCVM@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/default.htm or http://www.regulations.gov.

U.S. Department of Health and Human Services
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Guidance for Industry

Veterinary Feed Directive Common Format Questions and Answers

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

On December 12, 2013, the Food and Drug Administration (FDA) published a proposed rule to revise the veterinary feed directive (VFD) regulations in Title 21 of the Code of Federal Regulations section 558.6 (21 CFR 558.6), and introduce clarifying changes to the related definitions in 21 CFR 558.3. In June 2015 FDA published the final rule. Concurrently with the final rule, FDA published draft Guidance for Industry (GFI) #120 entitled “Veterinary Feed Directive Regulation Questions and Answers” to provide guidance on the final rule. FDA announced the availability of final GFI #120 (a small entity compliance guide) in September 2015.

A few of the comments in response to the proposed rule requested that FDA require a uniform veterinary feed directive (VFD) form. We declined this request because we thought that requiring a specific VFD form would be too prescriptive. However, we acknowledge that a common VFD format would help veterinarians, their clients (i.e., animal producers), and distributors (including feed mills) quickly identify relevant information on the VFD. Therefore, we are issuing this guidance to recommend a common VFD format. In this guidance, when we use the term “VFD,” we are referring to the form used to convey the VFD order.

FDA regulations at 21 CFR 514.1(b)(9) require that an animal drug sponsor who is seeking approval of a drug for use in or on feed as a VFD drug must submit copies of a VFD for review by FDA’s Center for Veterinary Medicine (CVM) “in a form that accounts for the information described under §§ 558.6(b)(3) and 558.6(b)(4)” as part of the application process. This guidance addresses the requirement for sponsor submission of a VFD found in § 514.1(b)(9), and recommends a common format for the information to be included on the VFD. Once the sponsor’s drug is approved, the VFD form provided by the sponsor will be made available for use by veterinarians when authorizing their client to obtain and use medicated feed containing the VFD drug. (Please note that a veterinarian is not required to use the sponsor’s form and may instead create his or her own VFD form.) This document also provides guidance concerning the elements that must be included on the VFD as required by § 558.6(b)(3) and the elements that may be included on the VFD as described in § 558.6(b)(4). Finally, this guidance provides examples that illustrate how a common VFD format might appear and how some information may be pre-populated on the VFD by the sponsor and subsequently completed with all of the
remaining relevant information filled out by the issuing veterinarian. This guidance only covers the contents and format of the VFD. Guidance for Industry #120, "Veterinary Feed Directive Regulation Questions and Answers," contains more comprehensive information about the VFD process, including information about the requirements for authorizing, manufacturing, distributing, and using VFD drugs in animal feed.

In general, FDA guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

II. VETERINARY FEED DIRECTIVE

A. Sponsor Submission of a Veterinary Feed Directive

1. What responsibilities does a sponsor have for creating and submitting a VFD to CVM?

As part of the application process for approval of a new animal drug for use in or on animal feed as a VFD drug, the drug sponsor is required to submit for FDA review three copies of a VFD in a format that accounts for the information described under §§ 558.6(b)(3) and 558.6(b)(4). (§ 514.1(b)(9)). Once the sponsor’s drug is approved, veterinarians have the option to use the sponsor’s VFD form when authorizing his or her client to obtain and use medicated feed containing the VFD drug.

2. Can a sponsor submit a VFD that does not include the VFD drug-specific information to meet the requirements of § 514.1(b)(9)?

No. A sponsor’s VFD must account for the VFD drug-specific information described in § 558.6(b)(3) and (b)(4) to meet the requirements of § 514.1(b)(9).

3. What VFD drug-specific information should be pre-populated on the VFD at the time a sponsor submits a VFD to CVM as part of the new animal drug application?

A VFD pre-populated by the sponsor likely will reduce the risk of a veterinarian making an error or leaving out required information when filling in the form. Sponsors should pre-populate the VFD with the information that is required to be included on the VFD by the VFD regulation found at § 558.6, and also with other information that does not require the veterinarian’s discretion when authorizing the VFD. In addition, the pre-populated VFD should contain areas

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1 We encourage sponsors with currently approved VFDs and veterinarians generating their own VFDs to also follow the VFD common format outlined in this guidance.

2 Alternatively, veterinarians may create their own VFD. When doing so, they may choose to follow the common format outlined in this guidance.
Contains Nonbinding Recommendations

designated on the form to account for the rest of the information that can only be provided by the veterinarian at the time the VFD is issued.

We recommend that, at a minimum, sponsors pre-populate the following information on the VFD submitted to CVM as part of the new animal drug application to reflect the conditions of approval, conditional approval, or index listing: (1) drug name(s); (2) drug level and duration of use (exact level or ranges as approved); (3) indication(s); (4) species and production class(es); (5) withdrawal time(s); (6) near the space where the veterinarian includes the expiration date, the maximum expiration date specified in the approval, conditional approval, or index listing, or 6 months if a date is not otherwise specified; (7) the maximum number of reorders (refills) permitted by the drug approval, conditional approval, or index listing or, if none are permitted, the statement, “Refills of this VFD are not permitted.”; (8) any special instructions specified on the approved labeling as necessary for use of the drug; (9) the statement, “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.”; and (10) cautionary statements (including warnings) necessary for use of the drug in conformance with the approval, conditional approval, or index listing. Special instructions, cautionary statements, and warnings found on the approved representative Type C medicated feed (Blue Bird) labeling should appear on the VFD.

4. What information should not be pre-populated on the VFD at the time a sponsor submits a VFD to CVM as part of the new animal drug application?

There is some information that a sponsor would generally be unable to pre-populate on the VFD because that type of information can only be filled in by the veterinarian once he or she has engaged with a particular client. This includes: (1) the client name, business or home address, and telephone number; (2) veterinarian name, address, and telephone number; (2) the premises at which the animals specified on the VFD are located; (3) the date of VFD issuance; (4) the VFD expiration date (a date not to exceed the date as specified in the approval, conditional approval, or index listing, or if not specified, not to exceed 6 months); (5) the approximate number of animals to be fed the VFD feed by the expiration date of the VFD; (6) the veterinarian’s special instructions; (7) the number of reorders (refills) authorized by the veterinarian (not to exceed the number permitted by the drug approval, conditional approval, or index listing, if any); (8) more specific identification of the animals to be treated as allowed by § 558.6(b)(4); (9) the veterinarian’s affirmation of intent for combination VFD drugs as described in § 558.6(b)(6); and (10) the veterinarian’s signature.

Several pieces of information required on the VFD result from the veterinarian's professional judgment and discretion but, based on the conditions and indications of use of the drug as set forth in the relevant approval, conditional approval, or index listing, the veterinarian may have limited options from which to choose. At a minimum, the VFD submitted to CVM by the

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3 The statements that are required to be on VFDs for approved, conditionally approved, and index listed drugs are different; thus, the sponsor should create a separate pre-populated VFD containing the relevant information for each category of legally marketed drugs (i.e., approved, conditionally approved, or index listed). Should the VFD reflect multiple indications in the same legal marketing category, we recommend that checkboxes be placed in front of each listed indication (with its associated species and production class, dose and duration of use, and withdrawal time) for the veterinarian to select which indication he or she is authorizing under the VFD.
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The sponsor should have identified space available for this information. The sponsor may pre-populate all of the optional information available to the veterinarian under the approval, conditional approval, or index listing by using formatting such as checkboxes or blanks for the veterinarian to indicate his or her decision. For example, if a VFD drug is a component of an approved, conditionally approved, or indexed combination VFD drug, the sponsor should include all three affirmation of intent statements on the VFD for the veterinarian to choose from. If a VFD drug is not a component of an approved, conditionally approved, or indexed combination VFD drug, the sponsor should include only the statement, “This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.”

Furthermore, when the veterinarian's options are limited by the approval, conditional approval, or index listing, the sponsor should provide blank space with information in a parenthetical that indicates the approved options available to the veterinarian. For example, the expiration date should have a blank line with a parenthetical that indicates the maximum expiration date allowed by the approval, conditional approval, or index listing (e.g., Exp. Date: ____ (not to exceed 21 days)). Another example is when the approval, conditional approval, or index listing allows the veterinarian to select a drug level from within a range. In that case, the sponsor should include space for the veterinarian to indicate the specific authorized drug level, as well as pre-populated parenthetical information about the range allowed by the approval, conditional approval, or index listing (e.g., Drug level: ____ g/ton (20-40 g/ton). If the drug level in the approval, conditional approval, or index listing is specified in units other than g/ton (e.g., mg/head/day or mg/unit body weight/day), then the sponsor should include space for the veterinarian to indicate the specific drug level in the feed in g/ton that corresponds with the dose level.

5. Is a sponsor allowed to further customize the VFD after CVM has approved the VFD?

Some drugs may be approved for more than one use (e.g., multiple indications). Sponsors of such drugs may wish to create VFDs that contain information relevant to more than one approved use of the drug in order to make them more user friendly for veterinarians. CVM will accept further revisions to the VFD after approval so long as the sponsor's customization: (1) conforms with the approved or conditionally approved application, or index listing; (2) includes all of the pre-populated information and spaces for the veterinarian-specified information that was included in the VFD(s) submitted to and approved by CVM; (3) includes all of the options available to a veterinarian consistent with the approval, conditional approval, or index listing; and (4) clearly organizes these options (for example, it should be clear which drug level, duration, withdrawal period, and cautionary statements, etc., correspond to a particular species, class, and/or indication). We think that this customization may, in some instances, reduce the possibility that veterinarians may accidentally omit required information or include information not allowed by the approval, conditional approval, or index listing.

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4 The statements that are required to be on VFDs for approved, conditionally approved, and index listed drugs are different; thus, the sponsor should create a separate pre-populated VFD containing the relevant information for each category of legally marketed drugs (i.e., approved, conditionally approved, or index listed).
6. Can a sponsor pre-populate information into the special instructions area of the VFD?

Generally, the special instructions area should be reserved for special instructions that appear on the approved representative Type C medicated feed (Blue Bird) labeling. A sponsor should pre-populate information in this area only if this information is always necessary for use of the VFD drug in conformance with the approval, conditional approval, or index listing, and is not already included elsewhere on the VFD as part of the information required by § 558.6(b)(3) or permitted by § 558.6(b)(4).

The special instructions area also provides space for the veterinarian to communicate information necessary for the appropriate treatment of the animals and/or the use of the VFD feed, relevant to the specific clients and patients for whom they are authorizing the VFD. Examples of this type of information include:

- Specific treatment instructions the veterinarian wants the client to follow that are allowable under the approval, conditional approval, or index listing, but may be impractical to include elsewhere on the VFD. For example, if a VFD drug can be used within a certain drug level range and the veterinarian would like the client to use a higher drug concentration within that range for a certain part of the treatment duration and a lower drug concentration within that range for another part of the treatment duration, the special instructions area could be used for that purpose.

- Specific response monitoring instructions the veterinarian wants the client to follow. For example, the veterinarian may want the client to monitor the animals daily and call if the symptoms do not improve after a certain number of days.

- Specific husbandry practices the veterinarian wants the client to follow to achieve maximum treatment results (e.g., weather or housing considerations);

- A reminder to the client to follow all labeling instructions. The veterinarian may want to specifically remind the client that if they choose to use the VFD drug in a combination feed the veterinarian has authorized with the affirmation statements, that labeling information such as withdrawal times and caution statements may differ and the client should comply with the information on the labeling for the combination feed.

7. Can the sponsor include other information on the VFD?

Because non-required information that is placed on the VFD can create confusion and make it more difficult to locate required information, we recommend limiting the information on the VFD to the required and discretionary information listed in §§ 558.6(b)(3) and (b)(4). We also recommend that any non-required information the veterinarian or sponsor may choose to include on a VFD be in a place and manner that does not interfere with the required and discretionary information listed in § 558.6(b).
8. Should the VFD have the proprietary name (trade name) or established name of the VFD drug(s)?

The name of the VFD drug is required to be included on the VFD. (§ 558.6(b)(3)(vi)). The veterinarian may choose to write either the established name (e.g., florfenicol, tilmicosin) or the proprietary name (trade name) of a specific VFD drug.

If the VFD lists a VFD drug by the proprietary name (trade name), the veterinarian may choose to specify that a substitution by the feed manufacturer is not allowed. For a sponsor-generated VFD that has the drug name pre-populated with the trade name, the sponsor may include a checkbox with the statement “[ ] Drug product substitution is not allowed if checked.” Nevertheless, if the sponsor does not include a checkbox on the VFD, the veterinarian may write on the VFD that substitution is not allowed as part of their authorization.

If the VFD lists a drug by the proprietary name but the veterinarian does not specify that a substitution is not allowed, the feed manufacturer may use either the approved pioneer or any approved generic VFD drug to manufacture the VFD feed provided that the approval for the drug being used is consistent with the information on the VFD order (e.g., approved for that indication, in that species and production class, and at the drug level specified on the order). However, the feed manufacturer may not substitute a generic VFD drug for a pioneer VFD drug in a combination VFD feed if the generic VFD drug is not a component of an approved combination VFD drug (21 U.S.C. 360b(a)).

If the VFD lists a VFD drug by an established name, the feed manufacturer may use the approved pioneer or any approved generic VFD drug to manufacture the VFD feed provided that the approval for the drug being used is consistent with the information on the VFD order (e.g., approved for that indication, in that species and production class, and at the drug level specified on the order). However, the feed manufacturer may not use a pioneer VFD drug or a generic VFD drug in a combination VFD feed if the pioneer or generic VFD drug is not a component of an approved combination VFD drug (21 U.S.C. 360b(a)).

B. Veterinary Feed Directive Information and Recommended Common Format

1. What information is required to be on the VFD and what information is discretionary? (§§ 558.6(b)(3) and (4))

The regulation at § 558.6(b)(3) requires that the following information be fully and accurately included on the VFD:

- the veterinarian’s name, address, and telephone number;
- the client’s name, business or home address, and telephone number;
- the premises at which the animals specified in the VFD are located;
- the date of VFD issuance;
- the expiration date of the VFD;
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- the name of the VFD drug(s);
- the species and production class of animals to be fed the VFD feed;
- the approximate number of animals to be fed the VFD feed by the expiration date of the VFD;
- the indication for which the VFD is issued;
- the level of VFD drug in the feed and duration of use;
- the withdrawal time, special instructions, and cautionary statements necessary for use of the drug in conformance with the approval;
- the number of reorders (refills) authorized, if permitted by the drug approval, conditional approval, or index listing;
- the statement: “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use), is not permitted.”;
- an affirmation of intent for combination VFD drugs as described in § 558.6(b)(6); and
- the veterinarian’s electronic or written signature.

Section 558.6(b)(4) permits the veterinarian to include on the VFD, at his or her discretion, the following additional information to identify more specifically the animals authorized to be fed the VFD feed:

- A more specific description of the location of the animals (for example, by site, pen, barn, stall, tank, or other descriptor the veterinarian deems appropriate);
- the approximate age range of the animals;
- the approximate weight range of the animals; and
- any other information the veterinarian deems appropriate to identify the animals specified in the VFD.

2. In what order should the information be included on the VFD?

The order the information is presented is important to ensure that the VFD can be understood and the correct medicated VFD feed manufactured and distributed. A common VFD format that a sponsor may use in order to meet the requirements of the regulations at §§ 514.1(b)(9) and 558.6(b) is shown in APPENDIX A. FDA believes that using this common format will help clients, veterinarians, and distributors (including feed mills) quickly identify relevant information on the VFD, reduce the potential for typographical or other errors on the VFD, and reduce errors in using the VFD to manufacture feed or feed the VFD feed to animals.
The common format in APPENDIX A contains the following features in the order listed below:

1. The contact information for the veterinarian and client. Including this information first allows the veterinarian, distributor, and client to easily see who authorized the VFD and who will be using the VFD;

2. Information about the VFD drug and the required statement about extralabel use. This information should be pre-populated by the sponsor on the VFD submitted to FDA as part of the new animal drug application. In cases where a veterinarian uses a VFD that has not been pre-populated with the VFD drug-specific information, grouping this information together helps the veterinarian identify and copy the appropriate information from the label and completely fill in all of the relevant drug information;

3. Information about the animals for which the VFD is being authorized, including the required and discretionary information;

4. The affirmation of intent statements for VFD drugs that are approved, conditionally approved, or indexed to be used in combination with other animal drugs. The statements also provide, if applicable, a checkbox for the veterinarian to affirm whether the use of the VFD drug is authorized: 1) in any approved, conditionally approved, or indexed combination containing the VFD drug as a component; 2) only in certain approved, conditionally approved, or indexed combinations containing the VFD drug as a component; or 3) in no approved, conditionally approved, or indexed combinations containing the VFD drug;

5. A section demarcated by compressed arrows that indicates the required drug withdrawal time. Separating and demarcating this information from the other drug approval information makes it easy for the client to locate on the VFD; and

6. Information on the issuance and expiration date, as well as the veterinarian’s signature. Including this required element last will help the veterinarian ensure that they have completed all of the required information on the VFD before applying his or her signature to the VFD.

APPENDIX B provides hypothetical examples of pre-populated VFDs using the features of this recommended common format, while APPENDIX C shows these same examples with all of the remaining relevant information subsequently filled out by the issuing veterinarian.

3. Do all three affirmation of intent statements need to be included for a VFD drug with no approved, conditionally approved, or indexed combination with other animal drug(s)?

No. If there is no approved, conditionally approved, or indexed combination of a VFD drug with other animal drug(s), only the first of the three affirmation of intent statements (the one specified in § 558.6(b)(6)(i)) should be included to make it clear to the veterinarian that this VFD drug is not a component of any approved, conditionally approved, or index listed combination. Such
inclusion would also minimize the potential for the reader to think that lack of an affirmation of intent statement on the VFD is a mistake, and thus think that the VFD is incomplete. When a VFD drug is a component of one or more approved, conditionally approved, or indexed combinations, all three affirmation of intent statements will need to be included, with checkboxes for the veterinarians to select their choice.

4. **How does the recommended common format apply to an electronic VFD?**

Any VFD, whether paper or electronic, is required to include the information specified by regulation. VFDs that are issued electronically may also follow this recommended common format.

5. **The examples in the appendices do not include space for additional information a sponsor may want to include, such as a logo. Can this information be included on the VFD?**

The examples provided in the appendices only include the required and discretionary information that is specified in the regulation. You may use these templates as the starting point to develop a VFD that may contain additional information (e.g., logo, sequential VFD number). However, keep in mind that additional information on the VFD can create confusion and make it more difficult to locate required information. We recommend that additional information on a VFD be included in a place and manner that does not interfere with the information listed in § 558.6(b).
APPENDIX A: BLANK VFD IN THE RECOMMENDED COMMON FORMAT

Veterinary Feed Directive

Veterinarian: ________________________________
Address: ________________________________
Phone: ________________________________
Fax or email (optional): ________________________________

Client: ________________________________
Address: ________________________________
Phone: ________________________________
Fax or email (optional): ________________________________

Drug(s) Name: ________________________________
Drug(s) Level: ________________________________
Duration of use: ________________________________

Species and Production class: ________________________________
Number of refills (if permitted by the drug approval): ________________________________

Indications for use (as approved): ________________________________

Caution (related to this medicated feed, if any): ________________________________

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED

Approximate Number of Animals: ________________________________

Premises: ________________________________

Other identification (e.g., age, weight) (optional): ________________________________

Special Instructions (if any): ________________________________

Affirmation of intent (for combination VFD Drugs) (check one box)*:

□ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

□ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Drug Level(s) and any Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

□ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

Withdrawal Time (if any): This VFD Feed must be withdrawn ___ days prior to slaughter

VFD Date of Issuance: ___________ (Month/Day/Year) VFD Expiration Date: ___________ (Month/Day/Year) (As specified in the approval, cannot exceed 6 months after issuance)

Veterinarian's Signature: ________________________________

All parties must retain a copy of this VFD for 2 years after the date of issuance. 21 CFR 558.6(a)(4)
APPENDIX B: EXAMPLES OF VFDS IN THE RECOMMENDED COMMON FORMAT PRE-POPULATED BY THE SPONSOR FOR SUBMISSION TO CVM

EXAMPLE 1: A PRE-POPULATED VFD FOR A VFD DRUG THAT IS NOT APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

Veterinarian: ________________________________  Client: ________________________________
Address: ___________________________________  Address: ________________________________
Phone: _____________________________________  Phone: _________________________________
Fax or email (optional): ________________________  Fax or email (optional): ____________________

Drug(s) Name: Mydrug  Drug(s) Level: 100 g/ton  Duration of use: 14 days

Species and Production class: Swine  Number of reorders (refills) authorized (if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with *Haemophilus paratuberculosis*

Caution (related to this medicated feed, if any): Not for use in pregnant sows

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED

Approximate Number of Animals: ______________

Premises: ___________________________________

Other identification (e.g., age, weight) (optional): _______________________________________

Special instructions (if any): ___________________________________________________________

Affirmation of intent (for combination VFD Drugs):

☒ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

Withdrawal Time (if any): This VFD Feed must be withdrawn _6_ days prior to slaughter

VFD Date of Issuance: ____/____/____ (Month/Day/Year)  VFD Expiration Date: ____/____/____ (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after Issuance)

Veterinarian's Signature: ________________________________

All parties must retain a copy of this VFD for 2 years after the date of issuance. 21 CFR 556.6(a)(4)
EXAMPLE 2: A PRE-POPULATED VFD FOR A VFD DRUG THAT IS APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

Veterinarian: ____________________________
Address: ________________________________
Phone: _________________________________
Fax or email (optional): ____________________

Client: _________________________________
Address: ________________________________
Phone: _________________________________
Fax or email (optional): ____________________

Drug(s) Name: Mydrug
Drug(s) Level: 109 g/ton
Duration of use: 14 days

Species and Production class: Swine
Number of orders (refills) authorized (if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with Bacterium pathologicum

Caution (related to this medicated feed, if any): Not for use in pregnant sows

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED

Approximate Number of Animals: ____________

Premises: ________________________________

Other identification (e.g., age, weight) (optional): ________________________________

Special Instructions (if any): ________________________________

Affirmation of intent (for combination VFD Drugs) (check one box)*:

☐ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Drug Levels and any Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

Withdrawal Time (if any): This VFD Feed must be withdrawn __ days prior to slaughter

VFD Date of Issuance: __________ (Month/Day/Year) VFD Expiration Date: __________ (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

Veterinarian’s Signature: ________________________________

All parties must retain a copy of this VFD for 2 years after the date of issuance. 21 CFR 558.6(a)(4)
APPENDIX C: EXAMPLES OF PRE-POPULATED VFDS IN THE RECOMMENDED COMMON FORMAT THAT HAVE SUBSEQUENTLY BEEN COMPLETED BY THE ISSUING VETERINARIAN

**EXAMPLE 1: A VFD DRUG THAT IS NOT APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)**

Veterinary Feed Directive

For Mydrug

<table>
<thead>
<tr>
<th>Drug(s) Name:</th>
<th>Mydrug</th>
<th>Drug(s) Level:</th>
<th>100</th>
<th>g/ton</th>
<th>Duration of use:</th>
<th>14 days</th>
</tr>
</thead>
</table>

Species and Production class: Swine

Number of refills (refills authorized if permitted by the drug approval): 0

Indications for use (as approved): For the treatment of Swine Disease associated with *Bacterium pathologicum*

Caution (related to this medicated feed, if any): Not for use in pregnant sows

**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED**

Approximate Number of Animals: 200

Premises: 777 Country Road, Anytown, Anystate 00000

Other Identification (e.g., age, weight) (optional): All animals are between 4 and 15 months of age

Special Instructions (if any): OK to move the swine to Barn 5 after treatment

Affirmation of intent (for combination VFD Drugs):

- This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

Withdrawal Time (days): This VFD Feed must be withdrawn 5 days prior to slaughter

VFD Date of Issuance: 05/15/17 (Month/Day/Year) VFD Expiration Date: 08/15/17 (Month/Day/Year) (as specified in the approval; cannot exceed 6 months after issuance)

Veterinarian's Signature: [Signature]

---

All parties must retain a copy of this VFD for 2 years after the date of issuance. 21 CFR 558.6(a)(4)
EXAMPLE 2: A VFD DRUG THAT IS APPROVED, CONDITIONALLY APPROVED, OR INDEXED FOR USE WITH OTHER ANIMAL DRUG(S)

Veterinary Feed Directive
For Mydrug

<table>
<thead>
<tr>
<th>Veterinarian: John Doe, DVM or VMD</th>
<th>Client: John Smith</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address: 123 Anystreet</td>
<td>Address: 456 Anystreet</td>
</tr>
<tr>
<td>Anytown, Anystate 00000</td>
<td>(business or home) Anytown, Anystate 00000</td>
</tr>
<tr>
<td>Phone: 111-111-1111</td>
<td>Phone: 111-111-1111</td>
</tr>
<tr>
<td>Fax or email (optional):</td>
<td>Fax or email (optional):</td>
</tr>
</tbody>
</table>

- **Drug(s) Name:** Mydrug
- **Drug(s) Level:** 100
- **Duration of use:** 14 days

- **Species and Production class:** Swine
- **Number of reorders (refills) authorized (if permitted by the drug approval):** 0

- **Indications for use (as approved):** For the treatment of Swine Disease associated with *Bacterium pathogenicum*

- **Caution (related to this medicated feed, if any):** Not for use in pregnant sows

**USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRALABEL USE) IS NOT PERMITTED**

- **Approximate Number of Animals:** 200
- **Premises:** FFF Country Road, Anytown, Anystate 00000
- **Other Identification (e.g., age, weight) (optional):** All animals are between 4 and 6 months of age
- **Special Instructions (if any):** OK to move the swine to Barn 5 after treatment

**Affirmation of intent (for combination VFD Drugs) (check one box):**

- □ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

- ☒ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component:

<table>
<thead>
<tr>
<th>Drug(s)</th>
<th>Drug Level(s) and any Special instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curex</td>
<td>100-200 g/tow; For complete information read the label for this combination</td>
</tr>
</tbody>
</table>

- □ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

**Withdrawal Time (if any):** This VFD Feed must be withdrawn 5 days prior to slaughter

- **VFD Date of Issue:** 05/15/17 (Month/Day/Year)
- **VFD Expiration Date:** 08/01/17 (Month/Day/Year) (As specified in the approval; cannot exceed 6 months after issuance)

**Veterinarian’s Signature:**

All parties must retain a copy of this VFD for 2 years after the date of issuance. 21 CFR 558.6(a)(4)
June 17, 2016

RE: Over-the-Counter (OTC) Animal Drugs Becoming Veterinary Feed Directive (VFD) or Prescription (Rx)

Dear Animal Food Facility:

We are contacting you because you are a potential distributor (retailer) of one or more animal drug products whose marketing status will be changing at the end of calendar year 2016. As you may be aware, over the past several years, the Food and Drug Administration (FDA) has taken important steps toward changing how antimicrobials that are important in human medicine ("medically important antimicrobials") can be legally used in feed or water for food-producing animals.

In Guidance For Industry (GFI) #213¹, the FDA asked animal drug sponsors of medically important antimicrobials administered in medicated feed or drinking water of food-producing animals to voluntarily remove from their product labels those indications for production purposes (i.e. growth promotion and feed efficiency), and bring the remaining therapeutic uses of these products under the oversight of a veterinarian by December 2016—changes that are critical to ensure these drugs are used judiciously and only when appropriate for specific animal health purposes.

All of the affected drug sponsors have committed to making the changes we requested. On January 1, 2017, the marketing status of the affected drugs will change from over-the-counter (OTC) to either prescription (Rx) status for drugs administered in medicated drinking water or veterinary feed directive (VFD) status for drugs administered in or on medicated feed. In some cases, drug sponsors may choose to withdraw a product approval completely. Drugs that have either an Rx or VFD marketing status can only be prescribed or authorized for use in animals by a licensed veterinarian. Distributors that are unable to meet the applicable State and Federal requirements for selling and distributing Rx and VFD animal drugs may no longer be able to sell these products once they have transitioned to their new marketing status. If this is the situation, distributors may need to return their unsold inventory to the manufacturer or wholesaler.

In addition, FDA recently published the VFD final rule, which outlines the revised process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all U.S. States with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes. The VFD final rule became effective

on October 1, 2015, and applies to veterinarians who authorize VFDs, distributors who distribute VFD feed, and clients who use VFD feed.

To ensure that a clear process is applied to implement the changes outlined in GFI #213 by the January 1, 2017 target date, CVM has provided additional information in the attached Appendices. These documents provide information on the products that will be transitioning from OTC status to Rx (water) or VFD (feed) status, VFD distributor requirements, and describe the timing of actions on addressing current and future inventory of products affected by GFI #213:

- Appendix 1 outlines the changes in marketing status of drugs administered in water that are transitioning from OTC to Rx status.
- Appendix 2 outlines changes in marketing status of drugs administered in or on feed that are transitioning from OTC to VFD status.
- Appendix 3 outlines requirements for distributors under the VFD final rule.
- Appendix 4 outlines the plan for transitioning approved products to the new (GFI #213-aligned) labeling requirements by January 1, 2017.

Please note that the documents attached are intended to offer a general understanding of the process and products involved. We understand and expect that issues and questions will arise as the process unfolds – please contact us as questions arise.

For any questions, please contact the FDA Center for Veterinary Medicine at AskCVM@fda.hhs.gov.

Sincerely,

/s/

William T. Flynn, D.V.M., M.S.
Deputy Director for Science Policy
U.S. Food and Drug Administration
Center for Veterinary Medicine

Appendices (4)
Appendix 1

Drugs Transitioning from Over-the-Counter (OTC) to Prescription (Rx) Status

Sales of Rx products
CVM expects that certain water soluble antimicrobial animal drug products will transition from over-the-counter (OTC) to prescription (Rx) marketing status on January 1, 2017, as part of FDA’s strategy to ensure the judicious use of medically important antimicrobial new animal drug products as outlined in Guidance for Industry #213 (GFI #213). Retailers and other establishments planning to distribute these products after January 1, 2017, will be subject to both State and Federal regulations applicable to the dispensing of Rx drugs.

CVM expects that the water soluble products listed below will transition from OTC to Rx marketing status on January 1, 2017. The prescribing or dispensing of Rx drug products for use in animals must be authorized by a licensed veterinarian under federal law and also under state law in most states. Once the approvals for the affected products are revised to reflect the transition from OTC to Rx marketing status, such products can only be used in compliance with regulations governing the dispensing of Rx drugs, even if the product still has the old OTC labeling.

FDA intends to initiate surveillance and compliance activities for the transitioned products beginning on January 1, 2017. Please contact the relevant state authority, such as the Board of Pharmacy, Board of Veterinary Medicine, or other agency regarding regulations that apply to the dispensing of Rx drugs in your state.

Refer to the complete list of affected applications at the following website for the most up-to-date information on actions taken with respect to specific antimicrobial drug products: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm.

FDA recommends that parties involved in the production and/or distribution of the affected products proactively manage product inventories in order to minimize the amount of OTC-labeled product that will remain on shelves at the time the marketing status of these products changes to Rx on January 1, 2017.

Water Soluble Drugs Transitioning From OTC to Rx Status
This list represents the antimicrobials approved for use in water that are affected by GFI #213. The complete list of affected applications will continue to be updated as changes are made, and can be located here:
http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm

Upon completion of the voluntary transition by drug sponsors of the following antimicrobial new animal drugs from OTC to Rx, all water uses of these drugs will require a prescription from a veterinarian as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the approved drug application:

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Examples of proprietary drug name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>chlorotetracycline</td>
<td>Aureomycin, Aureomycin, Chlora-Cycline, Chloronex,</td>
</tr>
<tr>
<td></td>
<td>Chlorotetracycline, Chlorotetracycline Bisulfate, Chlorotet-Soluble-O, CTC,</td>
</tr>
<tr>
<td></td>
<td>Fermycin, Pennchlor</td>
</tr>
<tr>
<td>erythromycin</td>
<td>Gallimycin</td>
</tr>
<tr>
<td>gentamicin</td>
<td>Garacin, Gen-Gard, GentaMed, Gentocin, Gentoral</td>
</tr>
<tr>
<td>lincomycin</td>
<td>Linco, Lincomed, Lincomix, Lincomycin, Lincomycin Hydrochloride,</td>
</tr>
<tr>
<td></td>
<td>LincoSol, Linmed-SP</td>
</tr>
<tr>
<td>lincomycin/spectinomycin*</td>
<td>Lincomycin S, Lincomycin-Spectinomycin, L-S, SpecLinx</td>
</tr>
<tr>
<td>neomycin</td>
<td>Biosol Liquid, Neo, Neomed, Neomix, Neomycin, Neomycin Liquid,</td>
</tr>
<tr>
<td></td>
<td>Neomycin Sulfate, Neo-Sol, Neosol, Neosol-Oral, Neovet</td>
</tr>
<tr>
<td>oxytetracycline</td>
<td>Agrimycin, Citratet, Medamycin, Oxymarine, Oxymycin, Oxy-Sol,</td>
</tr>
<tr>
<td></td>
<td>Oxytet, Oxytetracycline, Oxytetracycline HCL, Oxy WS, Pennox,</td>
</tr>
<tr>
<td></td>
<td>Terramycin, Terra-Vet, Tetravet-CA, Tetroxy, Tetroxy Aquatic, Tetroxy HCA</td>
</tr>
<tr>
<td>penicillin</td>
<td>Han-Pen, Penaqua Sol-G, Penicillin G Potassium, R-Pen, Solu-Pen</td>
</tr>
<tr>
<td>spectinomycin</td>
<td>Spectam</td>
</tr>
<tr>
<td>sulfadimethoxine</td>
<td>Agribon, Albon, Di-Methox, SDM, Sulfabiotic, Sulfadimethoxine,</td>
</tr>
<tr>
<td></td>
<td>Sulfadived, SulfaMed-G, Sulforal, Sulfasol</td>
</tr>
<tr>
<td>sulfamethazine</td>
<td>SMZ-Med, Sulf, Sulmet</td>
</tr>
<tr>
<td>sulfadiazine</td>
<td>S.Q. Solution, Sulf-Nox, Sulfadiazine Sodium, Sulfamethazine Solubilized, Sul-Q-Nox, Sulquin</td>
</tr>
<tr>
<td>tetracycline</td>
<td>Duramycin, Polyotic, Sulf/Tet, Sul-Tet, Supercycline, Terra-Vet, Tet,</td>
</tr>
<tr>
<td></td>
<td>Tetra-Bac, Tetracycline, Tetracycline Hydrochloride, Tetramed, Tetra-Sal, Tet-Sal, TC Vet</td>
</tr>
</tbody>
</table>

Note: apramycin, carbomycin/oxytetracycline*, chlorotetracycline/sulfamethazine*, streptomycin, sulfachloropyrazine, sulfachlorpyridazine, and sulfamerazine/sulfamethazine/sulfadiazine* are also approved for water use and are expected to transition to Rx status, but are not marketed at this time. If they return to the market on or after January 1, 2017, their use in water will require a prescription from a veterinarian.

*Fixed-ratio, combination drug
**Current Rx Water Soluble Drugs**

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Examples of proprietary drug names</th>
</tr>
</thead>
<tbody>
<tr>
<td>tylosin</td>
<td>Tylan, Tylomed, Tylosin, Tylosin Tartrate, Tylovet</td>
</tr>
</tbody>
</table>

This information was published online on January 19, 2016, and is available at: [http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482106.htm](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482106.htm). As the affected products transition, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates: [http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm](http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm)

**Additional Resources:**

- National Association of State Boards of Pharmacy:
  [https://www.nabp.net/boards-of-pharmacy](https://www.nabp.net/boards-of-pharmacy)
- List of drugs transitioning from over-the-counter (OTC) to prescription (Rx) Status, printer-friendly PDF:
Appendix 2

Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status

Drugs Transitioning From OTC to VFD Status

CVM expects that certain antimicrobial animal drug products approved for use in animal feed will transition from over-the-counter (OTC) to veterinary feed directive (VFD) marketing status on January 1, 2017, as part of FDA’s strategy to ensure the judicious use of medically important antimicrobial new animal drug products as outlined in Guidance for Industry #213 (GFI #213). The list below represents the antimicrobials approved for use in or on animal feed affected by GFI #213. The complete list of affected applications will continue to be updated as changes are made and can be located here:

http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm

Upon completion of the voluntary transition by animal drug sponsors of the following antimicrobial new animal drugs from OTC to VFD marketing status, all feed uses of the these drugs, alone and in a combination, will require a VFD as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the approved drug application:

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Examples of proprietary drug name(s)²</th>
</tr>
</thead>
<tbody>
<tr>
<td>chlortetracycline (CTC)</td>
<td>Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortetracycline, Deracin, Inchlor, Pennchlor, Pfichlor</td>
</tr>
<tr>
<td>chlortetracycline/sulfamethazine*</td>
<td>Aureo S, Aureomix S, Pennchlor S</td>
</tr>
<tr>
<td>chlortetracycline/sulfamethazine/penicillin*</td>
<td>Aureomix 500, Chlorachel/Pfichlor SP, Pennchlor SP, ChlorMax SP</td>
</tr>
<tr>
<td>hygromycin B</td>
<td>Hygromix</td>
</tr>
<tr>
<td>lincomycin</td>
<td>Lincomix</td>
</tr>
<tr>
<td>oxytetracycline (OTC)</td>
<td>TM, OXTC, Oxytetracycline, Pennox, Terramycin</td>
</tr>
<tr>
<td>oxytetracycline/neomycin*</td>
<td>Neo-Oxy, Neo-Terramycin</td>
</tr>
<tr>
<td>penicillin*</td>
<td>Penicillin, Penicillin G Procaine</td>
</tr>
<tr>
<td>sulfadimethoxine/ormetoprim*</td>
<td>Rofenaíd, Romet</td>
</tr>
<tr>
<td>tylosin</td>
<td>Tylan, Tylosin, Tylovet</td>
</tr>
<tr>
<td>tylosin/sulfamethazine*</td>
<td>Tylan Sulfag, Tylan Plus Sulfag, Tylosin Plus Sulfamethazine</td>
</tr>
<tr>
<td>virginiamycin</td>
<td>Stafac, Virginiamycin, V-Max</td>
</tr>
</tbody>
</table>

Note: apramycin, erythromycin, neomycin (alone), oleandomycin*, sulfamerazine, and sulfaquinoxaline are also approved for use in feed and are expected to transition to VFD status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a VFD.
Type A medicated articles used to manufacture medicated feed, all products may not be marketed at this time
*Fixed-ratio, combination drug
+Currently only approved for production uses

Current VFD Drugs

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Proprietary drug name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>avilamycin</td>
<td>Kavault</td>
</tr>
<tr>
<td>florfenicol</td>
<td>Aquafior, Nuflor</td>
</tr>
<tr>
<td>tilmicosin</td>
<td>Pulmotil, Tilmovet</td>
</tr>
</tbody>
</table>

Type A medicated articles used to manufacture medicated feed

This information was published online on January 19, 2016, and is available at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm. As the affected products transition from OTC to VFD marketing status, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates:
http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm

Additional Resources:

- Blue Bird Labels: http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm
Appendix 3

Requirements for Distributors under the VFD Final Rule

Sales of VFD products
Under VFD regulation, a "distributor" means any person who distributes a medicated feed containing a VFD drug to another person (21 CFR 558.3(b)(9)). Therefore, if you are a retailer or other establishment who will be selling animal feed containing a VFD drug, whether to the end user or another distributor, you will be considered a "distributor" under the VFD final rule, and are responsible for compliance with 21 CFR 558.6, including the distributor-specific requirements outlined below.

CVM expects that the medically important antimicrobials administered to food producing animals in medicated feed (see Appendix 2 above) will transition from OTC to VFD marketing status on January 1, 2017. A veterinary feed directive is not required for current OTC products transitioning to VFD status until January 1, 2017. On January 1, 2017, all products with approvals that have transitioned from OTC to VFD must be used in compliance with the VFD regulations, even if the product has the old OTC labeling. At the time of transitioning from OTC to VFD marketing status, these products will become subject to the requirements in the VFD rule that went into effect on October 1, 2015.

A lawful VFD is required to obtain and use medicated feed containing a VFD drug (VFD feed). Beginning January 1, 2017, FDA intends to initiate surveillance and compliance activities to ensure that the products making this transition are being used in compliance with the applicable VFD requirements.

FDA recommends that parties involved in the production and/or distribution of the affected VFD products proactively manage product inventories to limit the amount of OTC-labeled product that will remain on shelves when these products are transitioned to VFD status on January 1, 2017.

Internet pharmacies
A VFD drug is not a prescription drug. If an internet pharmacy distributes VFD feed to another distributor or to the end user/client, they would be considered a VFD distributor and therefore would need to notify FDA of their intent to distribute VFD feed and follow the distributor requirements in the VFD rule that went into effect on October 1, 2015, before distributing VFD feed. The requirements applicable to VFD distributors are discussed below. FDA has also

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issued a guidance (GFI #120) that addresses the requirements of the VFD rule in detail.

**Distributor Responsibilities - 21 CFR 558.6(c)**

If you intend to distribute an animal feed containing a VFD drug or a combination VFD drug, you must:

- file a one-time notice with FDA of intent to distribute animal feed containing a VFD drug;
- notify FDA within 30 days of any change in ownership, business name, or business address;
- fill a VFD order only if the VFD contains all required information;
- ensure that the animal feed you distribute containing the VFD drug or combination VFD drug complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug;
- ensure all labeling and advertising prominently and conspicuously display the following cautionary statement: “Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.”;
- retain VFD orders for two years from date of issuance;
- retain records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years;
- provide VFD orders for inspection and copying by FDA upon request;
- retain records of VFD manufacturing for 1 year in accordance with 21 CFR part 225 and make such records available for inspection and copying by FDA upon request;
- if you are the originating distributor (consignor), you must obtain an acknowledgement letter from the receiving distributor (consignee) before the feed is shipped; and
- if you are a consignor distributor, you are required to retain a copy of each consignee distributor’s acknowledgement letter for 2 years.

**“One-Time” Distributor Notification - 21 CFR 558.6(c)(5)**

If you intend to distribute animal feed containing a VFD drug or a combination VFD drug, you must file a one-time notice with FDA before you begin distributing VFD feed.

The VFD distributor notification letter can be done in a number of ways as long as it contains the following required information:

1. The distributor’s complete name and business address;
2. The distributor’s signature or the signature of the distributor’s authorized agent; and
3. The date the notification was signed.

A single notification may include multiple locations. For multiple locations, each address

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must be included in the notification. A company with multiple locations may send separate VFD distributor notifications for each location. Perhaps an easier way of doing it is to submit one letter stating their intent to distribute VFD feeds at each of their locations, including each location’s physical address. Both would be acceptable as long as they contain the required information mentioned above.

A letter from a company that states their intent to distribute at all of their locations, but fails to provide the address of each location would not be acceptable.

In addition, we would like to make clear that the locations listed in the VFD Distributor Notifications we receive are entered into a database, and a listing of VFD Distributors is published on the FDA.gov website available to the public.\(^5\)

The notice should be sent by mail or faxed to Division of Animal Feeds (HFV-220); FDA, Center for Veterinary Medicine; 7519 Standish Pl., Rockville, MD 20855; FAX: 240-453-6882.

You must also notify FDA within 30 days of any change in ownership, business name, or business address.

**Acknowledgment letter - 21 CFR 558.3(b)(11) and 21 CFR 558.6(c)(6)**

An acknowledgement letter is a letter that a distributor obtains from another distributor (the distributor receiving the VFD feed) when the distributor ships an animal feed containing a VFD drug in the absence of a valid VFD. Specifically, an “acknowledgement letter” is a written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee).

An acknowledgement letter must be provided either in hardcopy or through electronic media, and must affirm:

1. that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD;
2. that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgement letter; and
3. that the distributor has complied with the distributor notification requirements in 21 CFR 558.6(c)(5).

The acknowledgment letter allows a distributor to have VFD feed on hand so that when an end user/client gives him/her a valid VFD the distributor can fill the VFD immediately.

\(^5\) For example see: http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM096059.pdf
An acknowledgment letter may be written to cover one or more shipments of a VFD feed with an open-ended duration. In that instance, the acknowledgment letter must be kept for two years from the date of last shipment distributed under the acknowledgment letter.

Please note: an acknowledgment letter is different than a distributor notification. As discussed above, a distributor notification is the one-time notice by a distributor to the FDA of its intent to distribute a medicated feed containing a VFD drug.

Feed Manufacturing
If you manufacture medicated feed, you are required to have a medicated feed mill license if the VFD drug you use to manufacture a medicated feed is a Category II, Type A medicated article. A license is also required in some situations involving certain liquid and free-choice medicated feeds. As a licensed feed mill, you are subject to the cGMP requirements for a licensed feed mill in 21 CFR 225.

Recordkeeping
Depending on to whom you distribute VFD feed, the following applies:

<table>
<thead>
<tr>
<th>If you ship VFD feed to</th>
<th>Record Required</th>
<th>Record Retained for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clients (end-users) only</td>
<td>VFD (order)</td>
<td>2 years</td>
</tr>
<tr>
<td>Other distributors only</td>
<td>Acknowledgement letter(s) or VFD (order)</td>
<td>2 years</td>
</tr>
<tr>
<td>Both clients and other distributors</td>
<td>VFD (order) from clients or other distributors and acknowledgement letter(s) from other distributors</td>
<td>2 years</td>
</tr>
</tbody>
</table>

If you manufacture VFD feed, you also need:

Manufacturing Record

<table>
<thead>
<tr>
<th>Required per</th>
<th>Retained for</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 225 (cGMP)</td>
<td>1 year</td>
</tr>
</tbody>
</table>

Additional Resources:
- Veterinary Feed Directive (VFD):
  [http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm](http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm)
- Guidance for Industry #120, Veterinary Feed Directive Regulation Questions and Answers:
Page 12

- Safe Feed webpage:
  http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/default.htm
- Blue Bird Labels:
  http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm
Appendix 4

Plan for Transitioning to New Labeling by January 1, 2017

CVM’s primary goal is that beginning on January 1, 2017, all affected products (medically important antimicrobials approved for use in animal feed or water) are to be used in the market in accordance with the changes outlined in GFIs #209 and #213 as part of FDA’s strategy to ensure the judicious use of medically important antimicrobials in animal agriculture. This means that, as of that date, such products would no longer be used for production (i.e. growth promotion and feed efficiency) purposes and would only be used with the prior authorization of a licensed veterinarian.

The FDA sent a letter in September 2015 to each affected animal drug sponsor outlining the process of transitioning their products to remove approval for production use and to phase in veterinary oversight for the remaining therapeutic uses of these products by the end of December 2016. The letter also explained the approval process for each label change and outlined the materials sponsors need to submit to the agency in order to complete the transition.

Below are key time periods that were discussed in the letter to animal drug sponsors, and some of the different labeling you may see enter the market as animal drug sponsors manage product inventories and facilitate the transition to new labeling by the January 1, 2017, target date.

A. Between now and June 30, 2016

**Transitional labeling:** Between now and June 30, 2016, drug sponsors may use “transitional labels” provided with the existing product labeling and/or information that is printed on or affixed to the product labeling. If such “transitional labeling” is used, we would expect such labeling to be consistent with the following statements:

*Statement that applies to feed products:* Beginning January 1, 2017, this product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction:

"Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." 6

*Statement that applies to water products:* Beginning January 1, 2017, this product will require a prescription issued by a licensed veterinarian and will be subject to the following restriction:

"Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." 7

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6 21 CFR Sec. 558.6 (a) (6)
Statement that applies to all feed or water products with production indications:

Effective January 1, 2017, this product will no longer be approved for [insert all production indications as they appear on labeling] which means the use of this product for that [these] purpose[s] will no longer be legal.

We expect all agreements on new labeling to be in place and labeling supplement materials submitted to FDA by drug sponsors by no later than June 30, 2016. Therefore, after June 30, 2016, we have asked sponsors to use discretion in deciding whether to continue to apply “transitional labeling” to new product inventory.

Given the unique circumstances and the temporary nature of this “transitional labeling,” we informed sponsors that we would not object to them immediately labeling affected product with the above information. As such, distributors may see this “transitional labeling” on the market between now and June 30, 2016, and to a more limited extent, after June 30, 2016.

B. Between June 30, 2016 and January 1, 2017

Between June 30, 2016 and January 1, 2017, we expect the drug sponsors to begin manufacturing product containing the new labeling for distribution to the marketplace on or after January 1, 2017. New labeling could utilize stickers affixed to existing product labeling and/or new printed labeling.

For medicated feed products, sponsors will also need to generate updated Blue Bird labels. We have informed sponsors that it would be helpful to make available advance copies of the updated Blue Bird labels for feed manufacturers.

New animal drug sponsors have been encouraged to manage product inventory appropriately so that new labeling will not enter the market before January 1, 2017. Product labeled with new VFD drug labeling (restricting medicated feed containing the VFD drug to use by or on the order of a licensed veterinarian) will not include a “transitional statement” indicating the implementation begins January 1, 2017, and may be confusing.

Please note: a veterinary feed directive is not required to be issued by a licensed veterinarian for affected products transitioning from OTC to VFD status until January 1, 2017.

C. After January 1, 2017

As noted above, our primary goal is that beginning on January 1, 2017, all affected products are to be used in the market in accordance with the changes outlined in GFIs #209 and #213. This means that on that date, feed manufacturers will be expected to begin labeling medicated feeds with the new GFI #213-aligned Blue Bird labels.

\footnote{21 CFR Sec. 201.105 (a)(2)}
Our expectation is that beginning on January 1, 2017, product is either 1) labeled with "new" final printed label, 2) has a sticker affixed to the product that includes the "new" final label language, or 3) is labeled with the "transition label" statement(s) described above.

Additional Resources:

- Letter to Sponsors Regarding Implementation of GFI 213:
- Judicious Use of Antimicrobials
  http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm
Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status

Upon completion of their voluntary transition from OTC to VFD, all feed uses of the following drugs, alone and in a combination, will require a VFD as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the drug application:

**Drugs Transitioning From OTC to VFD Status**

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Examples of proprietary drug name(s)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>chlortetracycline (CTC)</td>
<td>Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortetracycline, Deracin, Inchlor, Pennchlor, Pfichlor</td>
</tr>
<tr>
<td>chlortetracycline/sulfamethazine*</td>
<td>Aureo S, Aureomix S, Pennchlor S</td>
</tr>
<tr>
<td>chlortetracycline/sulfamethazine/penicillin*</td>
<td>Aureomix 500, Chlorachel/Pfichlor SP, Pennchlor SP, ChlorMax SP</td>
</tr>
<tr>
<td>hygromycin B</td>
<td>Hygromix</td>
</tr>
<tr>
<td>lincomycin</td>
<td>Lincomix</td>
</tr>
<tr>
<td>oxytetracycline (OTC)</td>
<td>TM, OXTC, Oxytetracycline, Pennox, Terramycin</td>
</tr>
<tr>
<td>oxytetracycline/neomycin*</td>
<td>Neo-Oxy, Neo-Terramycin</td>
</tr>
<tr>
<td>penicillin*</td>
<td>Penicillin, Penicillin G Procaine</td>
</tr>
<tr>
<td>sulfadimethoxine/ormetoprim*</td>
<td>Rofenaid, Romet</td>
</tr>
<tr>
<td>tylosin</td>
<td>Tylan, Tylosin, Tylovet</td>
</tr>
<tr>
<td>virginiamycin</td>
<td>Stafac, Virginiamycin, V-Max</td>
</tr>
</tbody>
</table>

**Note:** apramycin, erythromycin, neomycin (alone), oleandomycin*, sulfamerazine, and sulfadinoxine are also approved for use in feed and are expected to transition to VFD status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a VFD.

$Type A medicated articles used to manufacture medicated feed, all products may not be marketed at this time.

*Fixed-ratio, combination drug

+Currently only approved for production uses

**Current VFD Drugs**

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Proprietary drug name(s)$</th>
</tr>
</thead>
<tbody>
<tr>
<td>avilamycin</td>
<td>Kavault</td>
</tr>
<tr>
<td>florfenicol</td>
<td>Aquaflor, Nuflor</td>
</tr>
<tr>
<td>tilmicosin</td>
<td>Pulmotil, Tilmovet</td>
</tr>
<tr>
<td>tylvalosin</td>
<td>Aivlosin</td>
</tr>
</tbody>
</table>

$Type A medicated articles used to manufacture medicated feed

This information is up-to-date as of August 8, 2016. As the industry transitions, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates:

http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
Veterinary Feed Directive for Swine
Aureomycin®
(chlortetracycline)

Indications, Drug Level in Medicated Feed, and Duration of Use: (select one and specify additional required information)

☐ 1) Swine: Control of porcine proliferative enteropathies (ileitis) caused by Lawsonia intracellularis susceptible to chlortetracycline.
   Drug Concentration: _______g/ton (to provide 10 mg/lb body weight/day, which is equivalent to approximately 400 g/ton)
   Duration of use:______days (Feed for not more than 14 days)

☐ 2) Swine: Treatment of bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis and bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline.
   Drug Concentration: _______g/ton (to provide 10 mg/lb body weight/day, which is equivalent to approximately 400 g/ton)
   Duration of use:______days (feed for not more than 14 days)

☐ 3) Swine: Reduction in the incidence of cervical lymphadenitis (jowl abscesses) caused by Group E Streptococci susceptible to chlortetracycline.
   Drug Concentration: _______g/ton (50 to 100 g/ton)
   Duration of use:______days

☐ 4) Breeding Swine: Control of leptospirosis (reducing the incidence of abortion and shedding of leptospirea) caused by Leptospira pomona susceptible to chlortetracycline.
   Drug Concentration: _______g/ton
   Duration of use:______days (feed continuously for not more than 14 days)

USE OF FEED CONTAINING THIS VETERINARY FEED DIRECTIVE (VFD) DRUG IN A MANNER OTHER THAN AS DIRECTED ON THE LABELING (EXTRA-LABEL USE) IS NOT PERMITTED.

Approximate number of Swine to be treated:

Premise or Location of animals:

Special Instructions and/or other animal identifications:

Affirmation of Intent (for combination VFD drugs): check the appropriate box:

☐ This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs.

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.
   (List the specific approved combination)

☐ This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.

Withdrawal Period: No withdrawal period is required.

Date of VFD Issuance:______(dd/mm/yyyy)

Date of VFD Expiration:______(dd/mm/yyyy)

(Cannot exceed 6 months after issuance)

Veterinarian’s signature: ________________________________